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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,266	08/22/2003	E. Ann Hallinan	S0 3370/2 US	9451

7590 09/09/2004

Pharmacia Corporation  
 Global Patent Department  
 Post Office Box 1027  
 Chesterfield, MO 63006

EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/646,266

**Applicant(s)**

HALLINAN, E. ANN

**Examiner**

Hector M Reyes

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**Restriction/Election Request**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, IN PART, drawn to a crystal form of 2-amino-7-(ethanimidoamino)-2-methylhept-5-enoic acid, wherein the said salt is not embraced in the salts described in claims 2 and 3, classified in class 562, subclass 460. A single disclosed species is herein requested for search purposes. This group may be subjected to further restriction.
- II. Claims 1, IN PART, and 2, 3 and 4, drawn to a crystal form of 2-amino-7-(ethanimidoamino)-2-methylhept-5-enoic acid wherein the said salts are described in claims 2 and 3 and pharmaceutical compositions comprising the same, classified in class 562, subclass 460. A single disclosed species is herein requested for search purposes.
- III. Claims 5-7<sup>1</sup> drawn to methods for the prophylaxis OR treatment of any clinical condition in a mammal for which an inhibitor of nitric oxide synthase is indicated and method of use of compounds described in claim 1 in the manufacture of medicaments, classified in different classes and subclasses. This group may be subjected to further restriction.

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<sup>1</sup> On page 24 it is presumed that claim 6 is partially presented. Notice that claim 23 ends with claim 5 but there is no indication of where claim 6 starts. By the subject matter in page 24, it is presumed that the said claim 6 is drawn to a method of using. Applicant should provide the full body claim of claim 6.

- IV. Claim 8, drawn to a synthetic preparation method for preparing compounds described in the said claim. Classified in class 562 and subclass 460.

The inventions are distinct, each from the other because of the following reasons:

Group II and I are drawn to two different sets of crystal forms having presumably different method of preparation. Indeed, a reference disclosing or suggesting any one of the above groups does not anticipates or suggests the remaining group under the meaning of 35 USC 102 or 35 USC 103, respectively.

Inventions II, I and Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are known compounds in the art that are inhibitors of nitric oxide, therefore the process of using can be practiced with an alternative compound not embraced in the instant claims.

Inventions II and I and invention IV are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case it is presumed that the compounds can be prepared by an alternative process, thus Group IV is different from Group I and II.

Because these inventions are distinct for the reasons given above and the search required for any of the groups is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the case that any of the Groups I or II are elected, the Examiner would be kindly willing to rejoin the process to prepare the said elected compounds limited to the same allowable scope of the elected compounds and provided claims are free from ANY 112 issues.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

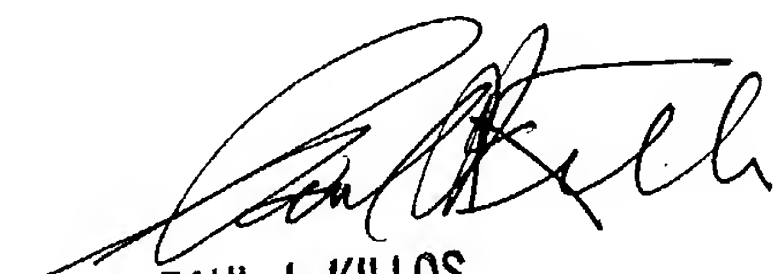
### **CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0961. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rita Desai can be reached on (571) 272-0684. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Hector M. Reyes PhD JD  
Reg. # P-54,846  
AU 1625  
September 7, 2004

  
PAUL J. KILLOS  
PRIMARY EXAMINER